06-23-00 A

Express Mail Label No.: EL559134451US

NEW UTILITY PATENT APPLICATION TRANSMITTAL (Large Entity) *(Only for new nonprovisional applications under 37 C.F.R. 1.53(b))*	Docket No. S63.2-9216
	Total Pages in this Submission *(including checks and postcard)* 26

Box Patent Application
Commissioner for Patents
Washington, D.C. 20231

Transmitted herewith for filing under 35 U.S.C. 111(a) and 37 C.F.R. 1.53(b) is a new utility patent application for an invention entitled: Improved Longitudinally Flexible Expandable Stent

and invented by: Brian J. Brown, Michael L. Davis

If a CONTINUATION APPLICATION, *check appropriate box and supply the requisite information:*
☒ **Continuation** ☐ **Divisional** ☐ **Continuation-in-part (CIP)** of prior application No.: 08/511,076 filed August 3, 1995 which is a continuation-in-part of application No. 08/396,569 filed March 1, 1995

Enclosed (in addition to the 4 pages of this transmittal) are: **4 pages**

Application Elements

1. ☒ **Filing fee as calculated below:**
   a. ☐ **filing fee is NOT ENCLOSED - fee will be paid at the time of responding to the Notice of Missing Parts -- DO NOT CHARGE DEPOSIT ACCOUNT**
   b. ☒ **a check in the amount of $690.00 to cover the filing fee is enclosed.** **1 pages**
   c. ☐ **charge to Deposit Account as authorized at Item 2(a) on next page.**

FEE CALCULATION AND C L A I M S					
For	**No. Filed**	**No. Allowed**	**No. Extra**	**Rate**	**Fee**
Total Claims	12	- 20 =	0	x $18.00	$ 0.00
Indep. Claims	2	- 3 =	0	x $78.00	$ 0.00
				BASIC FEE	$690.00
				TOTAL FILING FEE	$690.00

continued on next page.....

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NEW UTILITY PATENT APPLICATION TRANSMITTAL (Large Entity) *(Only for new nonprovisional applications under 37 C.F.R. 1.53(b))*	Docket No. S63.2-9216
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☒ Power of Attorney filed in parent application.

7. ☒ Incorporation by Reference *(usable if Box 5b is checked)*
The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 5b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

8. ☐ Computer Program in Microfiche *(Appendix)* ___ pages

9. ☐ Nucleotide and/or Amino Acid Sequence Submission ___ pages
(if applicable, all must be included)
   a. ☐ Paper Copy
   b. ☐ Computer Readable Copy *(identical to computer copy)*
   c. ☐ Statement Verifying Identical Paper and Computer Readable Copy

Accompanying Application Parts

10. ☒ Assignment Papers: ___ pages
   a. ☐ Assignment Recordation Cover Sheet (Form PTO 1595)
   b. ☐ Assignment
   c. ☐ A check in the amount of $___ to cover the Recordal Fee
   d. ☒ Previously recorded on August 3, 1995, Reel 7632, Frames 0502-0503

11. ☐ English Translation Document *(if applicable)* ___ pages

12. ☐ Information Disclosure Statement: ___ pages
   a. ☐ PTO Form 1449 b. ☐ Copies of IDS Citations

13. ☒ Preliminary Amendment 4 pages

14. ☒ Acknowledgement Postcard 1 page

15. ☒ Form of Mailing - Express Mail *(Specify Label No.)*: EL559134451US

16. ☐ Certified Copy of Priority Document(s) *(if foreign priority is claimed)* ___ pages

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NEW UTILITY PATENT APPLICATION TRANSMITTAL (Large Entity) *(Only for new nonprovisional applications under 37 C.F.R. 1.53(b))*	Docket No. S63.2-9216
	Total Pages in this Submission *(including checks and postcard)* 26

17. ☒ Additional Enclosures *(please identify below)*: 3 pages
   - ☒ Constructive Petition for Extension of Time and Fee Authorization Pursuant to 37 C.F.R. §1.136(a)(3) - 1 page
   - ☒ Correspondence Address form - 1 page
   - ☒ Limited Authorization to Act on Behalf of Assignee Regarding Certain Patent Matters Effective Through: December 31, 2000 - 1 page

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: June 22, 2000

By: _____

Jonathan Grad
Registration No.41,795

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F:\WPWORK\JG\9216-TRA.621

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Brown et al.
Application No.:	Not assigned yet
Filed:	Concurrently herewith
For:	IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT
Examiner:	Not assigned yet
Group Art Unit:	Not assigned yet

Commissioner for Patents
Washington, D.C. 20231

Docket No.: S63.2-9216

PRELIMINARY AMENDMENT

Before calculating the filing fee and beginning examination of this application, please amend the application as follows:

In the Specification:

On page 1, please delete lines 3-5 and replace them with the following text:

--This application is a continuation of US Application No. 08/511,076, filed August 3, 1995 which is a continuation-in-part of US Application No. 08/396,569, filed March 1, 1995, the contents of both of which are incorporated herein in their entirety by reference.--

In the claims:

Please cancel claims 1-8.

Please add new claims 9- 20 as follows:

--9.(New) A thin-walled, cylindrical stent formed from a single piece of metal, the stent having a nominal diameter when fully radially deployed into a vessel of the human body and having a longitudinal direction parallel to the axial axis of the cylindrical stent, the stent further comprising a multiplicity of sets of strut members with each set of strut members forming a circumferentially extending closed structure with adjacent sets of strut members being coupled each to the other by connectors, said stent having a proximal end, a distal end and a center

section located approximately half-way between said proximal and distal ends, said stent having two types of circumferentially extending sets of strut members, a first type of set of strut members and a second type of set of strut members, the first type of set of strut members having a shorter total circumferential length as compared to the total circumferential length of the second type of set of strut members, the stent when radially deployed to its nominal diameter having the first type of set of strut members having greater radial rigidity as compared to the second type of set of strut members.

10.(New) The stent as recited in claim 9 where said first type of set of strut members has a length in the longitudinal direction that is less than the length in the longitudinal direction of said second type of set of strut members.

11.(New) The stent as recited in claim 9 where there is at least one of the first type of set of strut members at said center section of the stent.

12.(New) The stent as recited in claim 9 where said stent is radially expanded responsive to inflation of a balloon onto which balloon the stent is mounted.

13.(New) The stent as recited in claim 9 where said stent is a radially self-expanding stent.

14.(New) The stent as recited in claim 9 where said stent is a mechanically expandable stent.

15.(New) The stent as recited by claim 9 where there is at least one of the second type of set of strut members situated at said proximal end of the stent.

16.(New) The stent as recited by claim 9 where there is at least one of the second type of set of strut members situated at said distal end of the stent.

17.(New) The stent of claim 9 wherein the connectors are disposed at an oblique angle relative to the longitudinal axis of the stent.

18.(New) A stent having a nominal diameter when fully radially deployed into a vessel of the human body and having a longitudinal direction parallel to the axial axis of the stent, the stent further comprising a multiplicity of sets of strut members with each set of strut members forming a circumferentially extending closed structure with adjacent sets of strut members being coupled each to the other by connectors, said stent having a proximal end, a distal end and a

center section located approximately half-way between said proximal and distal ends, said stent having two types of circumferentially extending sets of strut members, a first type of set of strut members and a second type of set of strut members, the first type of set of strut members having a shorter total circumferential length as compared to the total circumferential length of the second type of set of strut members, the stent when radially deployed to its nominal diameter having the first type of set of strut members having greater radial rigidity as compared to the second type of set of strut members.

19.(New) The stent of claim 18 wherein the connectors are disposed at an oblique angle relative to the longitudinal axis of the stent.

20.(New) The stent of claim 18 wherein the circumferentially extending closed structure is in the form of a cylindrical zig-zag.--

REMARKS

Claims 1-8 have been canceled and new claims 9-18 have been added. Support for new claims 9-20 is found in Fig. 4 of the specification as well as on page 5, lines 4-8 of the specification. Further support for new claim 12 is found on page 1, lines 22-24 and 30 of the specification. Further support for new claim 13 and 14 is found in the specification on page 5, lines 10-12. No new matter has been added by the amendments.

In accordance with 37 CFR 1.607(c), Applicant notes that many of the above claims correspond substantially to claims from US 5,913,895 to Burpee et al., issued June 22, 1999. A table indicating the correspondence is provided below.

Claim in instant application	Claim in Burpee
9	1
10	2
11	9
12	13
13	14
18	1

Applicant notes, however, that the correspondence identified above is not intended to constitute a statement that the scope of the claims is identical.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: June 22, 2000

By: ______________________
Jonathan Grad
Registration No.: 41,795

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DOCKET NO. S63.2-9216

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
APPLICATION FOR UNITED STATES LETTERS PATENT

INVENTOR(S): Brian J. Brown, Michael L. Davis

TITLE: IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT

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IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT

This application is a Continuation of application Serial No. 08/396,569, filed March 1, 1995, the disclosure of which is hereby incorporated by reference.

Field of the Invention

This invention relates to an endoprosthesis device for implantation within a body vessel, typically a blood vessel. More specifically, it relates to a tubular expandable stent of improved longitudinal flexibility.

Background of the Invention

Stents are placed or implanted within a blood vessel for treating stenoses, strictures or aneurysms therein. They are implanted to reinforce collapsing, partially occluded, weakened, or dilated sections of a blood vessel. They have also been implanted in the urinary tract and in bile ducts.

Typically, a stent will have an unexpanded (closed) diameter for placement and an expanded (opened) diameter after placement in the vessel or the duct. Some stents are self-expanding and some are expanded mechanically with radial outward force from within the stent, as by inflation of a balloon.

An example of the latter type is shown in U.S. Patent No. 4,733,665 to Palmaz, which issued March 29, 1988, and discloses a number of stent configurations for implantation with the aid of a catheter. The catheter includes an arrangement wherein a balloon inside the stent is inflated to expand the stent by plastically deforming it, after positioning it within a blood vessel.

A type of self-expanding stent is described in U.S. Patent No. 4,503,569 to Dotter which issued March 12, 1985, and discloses a shape memory stent which expands to an implanted configuration with a change in temperature. Other types of self-expanding stents not made of shape memory material are also known.

This invention is directed to stents of all these types when configured so as to be longitudinally flexible as described in detail hereinbelow. Flexibility is a desirable feature in a stent so as to conform to bends in a vessel. Such stents are known in the prior art. Examples are shown in U.S. Patent No. 4,856,516 to Hillstead; U.S. Patent No. 5,104,404 to Wolff; U.S. Patent No. 4,994,071 to MacGregor; U.S. Patent No. 5,102,417 to Palmaz; U.S. Patent No. 5,195,984 to Schatz; U.S. Patent No.

5,135,536 to Hillstead; U.S. Patent 5,354,309 to Shepp-Pesch et al.; EPO Patent Application 0 540 290 A2 to Lau; EPO Patent Application No. 0 364 787 B1 to Schatz, and PCT Application WO 94/17754 (also identified as German Patent Application 43 03 181).

Generally speaking, these kinds of stents are articulated and are usually formed of a plurality of aligned, expandable, relatively inflexible, circular segments which are interconnected by flexible elements to form a generally tubular body which is capable of a degree of articulation or bending. Unfortunately, a problem with such stents is that binding, overlapping or interference can occur between adjacent segments on the inside of a bend due to the segments moving toward each other and into contact or on the outside of a bend the segments can move away from each other, leaving large gaps. This can lead to improper vessel support, vessel trauma, flow disturbance, kinking, balloon burst during expansion, and difficult recross for devices to be installed through already implanted devices and to unsupported regions of vessel.

A diamond configuration with diagonal connections between each and every diamond of each segment is also known but such closed configurations lack flexibility.

It is an object of this invention to provide a longitudinally flexible stent of open configuration that avoids these problems and exhibits improved flexibility (radially and longitudinally) in the stent body segments thereof rather than in flexible joints between the segments.

Summary of the Invention

To this end, the invention provides a tubular expandable stent, comprising: a plurality of cylindrical shaped open cylindrical segments aligned on a common longitudinal axis to define a generally tubular stent body, each segment being defined by a member formed in an undulating flexible pattern of interconnected substantially parallel struts with pairs thereof having alternating interconnecting end portions to define the periphery of the expandable stent segment, and in which the connected end portions of paired struts in each segment, before the stent is expanded, are positioned substantially opposite to connected end portions of paired struts in adjacent segments. The segments are interconnected by a plurality of interconnecting elements extending from some of the connected end portions on one segment to some of

the connected end portions on adjacent segments in such a manner that there are three or more legs between points of connection from one side of each segment to its other side. Additionally, the connecting elements extend angularly from connecting end portion of one segment to connecting end portion of an adjacent segment, not to an opposite connecting end portion on an adjacent segment, whereby upon expansion of the stent the adjacent segments are displaced relative to each other about the periphery of the stent body to accommodate flexing of the stent within paired struts without interference between adjacent segments, rather than by means of articulating flexible connectors between segments. As a result, the connectors between the segments are not intended to flex or bend under normal use.

Brief Description of the Figures

Figure 1 shows a flat view of an unexpanded stent configuration according to the invention.

Figure 2 shows the pattern of Figure 1 in a tubular, unexpanded stent.

Figure 3 shows an expanded stent of the configuration shown in Figure 1.

Figure 4 shows a flat view of an alternate unexpanded stent configuration according to the invention.

Best Mode Description of the Invention

Turning to the Figures, Figure 1 and Figure 2 show a fragmentary flat view of an unexpanded stent configuration and the actual tubular stent (unexpanded), respectively. That is, the stent is shown for clarity in Figure 1 in the flat and may be made from a flat pattern 10 (Figure 1) which is formed into a tubular shape by rolling the pattern so as to bring edges 12 and 14 together (Figure 1). The edges may then joined as by welding or the like to provide a configuration such as that shown in Figure 2.

The configuration can be seen in these Figures to be made up of a plurality of adjacent segments generally indicated at 16, each of which is formed in an undulating flexible pattern of substantially parallel struts 18. Pairs of struts are interconnected at alternating end portions 19a and 19b. As is seen in Figure 1, the interconnecting end portions 19b of one segment are positioned opposite interconnecting end portions 19a of adjacent segments. The end portions as shown are

generally elliptical but may be rounded or square or pointed or the like. Any configuration of end portions is acceptable so long as it provides an undulating pattern, as shown. When the flat form 10 is formed into an unexpanded tube as shown in Figure 2, the segments are cylindrical but the end portions 19 of adjacent segments remain in an opposed position relative to each other.

A more preferred method of manufacture begins with a thin walled tube which is then laser cut to provide the desired configuration. It may also be chemically etched or EDM'd (electrical discharge machined) to form an appropriate configuration.

Interconnecting elements 20 extend from one end portion 19 of one segment 16 to another end portion 19 of another adjacent segment 16 but not to an oppositely positioned end portion 19 of an adjacent segment 16. There are at least three struts included between the points on each side of a segment 16 at which an interconnecting element 20 contacts an end portion 19. This results in the interconnecting elements 20 extending in an angular direction between segments around the periphery of the tubular stent. Interconnecting elements 20 are preferably of the same length but may vary from one segment to the other. Also, the diagonal direction may reverse from one segment to another extending upwardly in one case and downwardly in another, although all connecting elements between any pair of segments are substantially parallel. Figure 1, for example shows them extending downwardly, right to left. Upwardly would extend up left to right in this configuration.

As a result of this angular extension of the interconnecting elements 20 between adjacent segments and loops, upon expansion of the stent as seen in Figure 3, the closest adjacent end portions 19 between segments 16 are displaced from each other and are no longer opposite each other so as to minimize the possibility of binding or overlapping between segments, i.e., pinching.

The number of interconnecting elements 20 may vary depending on circumstances in any particular instance. Three per segment are satisfactory for the configuration shown and at least three will be used typically.

The alternate design shown in Figure 4 includes longer struts 18a in the two end segments 16a than in the intermediate segments 16. This allows the end segments (16a) to have less compression resistance than the intermediate segments (16), providing a more gradual transition from the native vessel to the support structure of the stent. Otherwise, the configuration is the same as that shown in Figure 1.

As already indicated, this invention is applicable to self-expanding configurations, mechanically expandable configurations and to a wide variety of materials, including both metal and plastic and any other material capable of functioning as an expandable stent. For example, the stent may be of metal wire or ribbon such as tantalum, stainless steel or the like. It may be thin-walled. It may be of shape memory alloy such as Nitinol or the like, etc.

The above Examples and disclosure are intended to be illustrative and not exhaustive. These examples and description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto.

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What is claimed is as follows:

1. A tubular, flexible, expandable stent, comprising:

a plurality of cylindrical shaped segments aligned on a common longitudinal axis to define a generally tubular stent body, each segment being defined by a member formed in an undulating pattern of interconnected substantially parallel struts to define the periphery of the expandable stent body, and in which adjacent pairs of struts in a given segment are interconnected at opposite ends, interconnected ends of one segment being positioned substantially opposite to interconnected ends of an adjacent segment, and

a plurality of interconnecting elements each extending from an end of paired struts on one segment to an end of paired struts on an adjacent segment, the elements extending angularly from one end on one segment to another end, not to an opposite end, on an adjacent segment, the distribution of the elements being such that there are at least three struts between each connecting point on opposite sides of the segments,

whereby, upon expansion of the stent, the paired struts of the adjacent segments are displaced relative to each other about the periphery of the stent body to accommodate longitudinal flexing of the stent within the segments and without interference between adjacent segments.

2. The stent of claim 1 wherein the material of which it is comprised is metal.

3. The stent of claim 2 wherein the metal is a shape memory alloy.

4. The stent of claim 2 wherein the stent is a thin-walled tubular member.

5. The stent of claim 1 in a self-expanding configuration.

6. The stent of claim 1 in a mechanically expandable configuration.

7. The stent of claim 1 wherein the interconnecting elements between adjacent segments are of the same length.

8. The stent of claim 1 wherein the stent includes end segments and intermediate segments and the end segments of the stent include longer struts than the intermediate segments of the stent.

Abstract of the Disclosure

IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT

Segmented articulatable stent of open structure comprised of end-connected struts making up the segments with angular interconnects between segments.

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Fig. 1

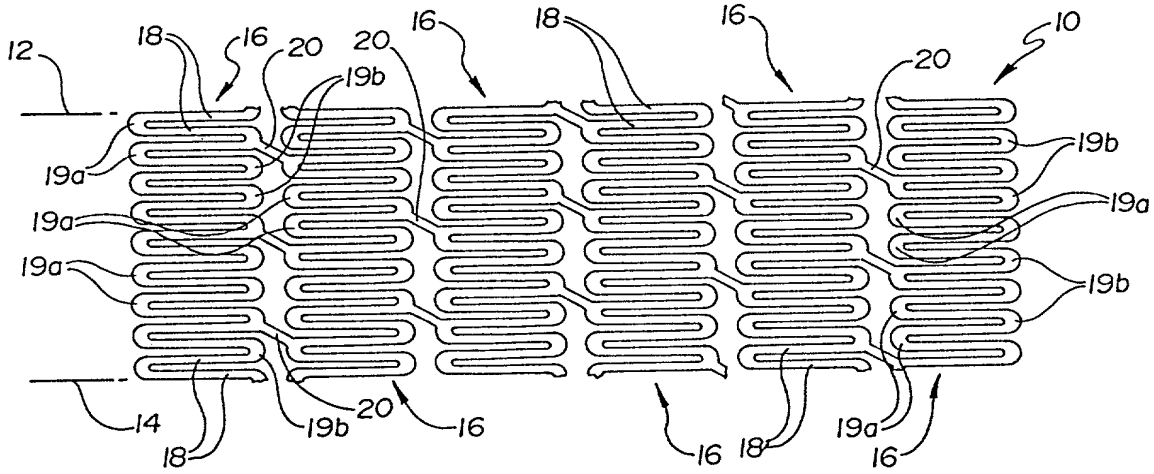
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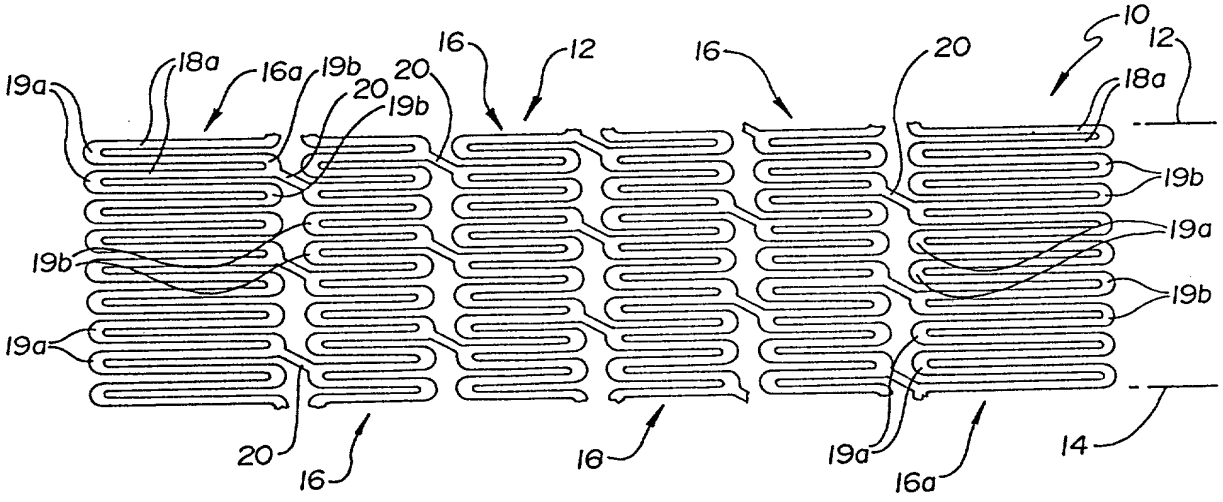
Fig. 4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16a
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Fig. 2

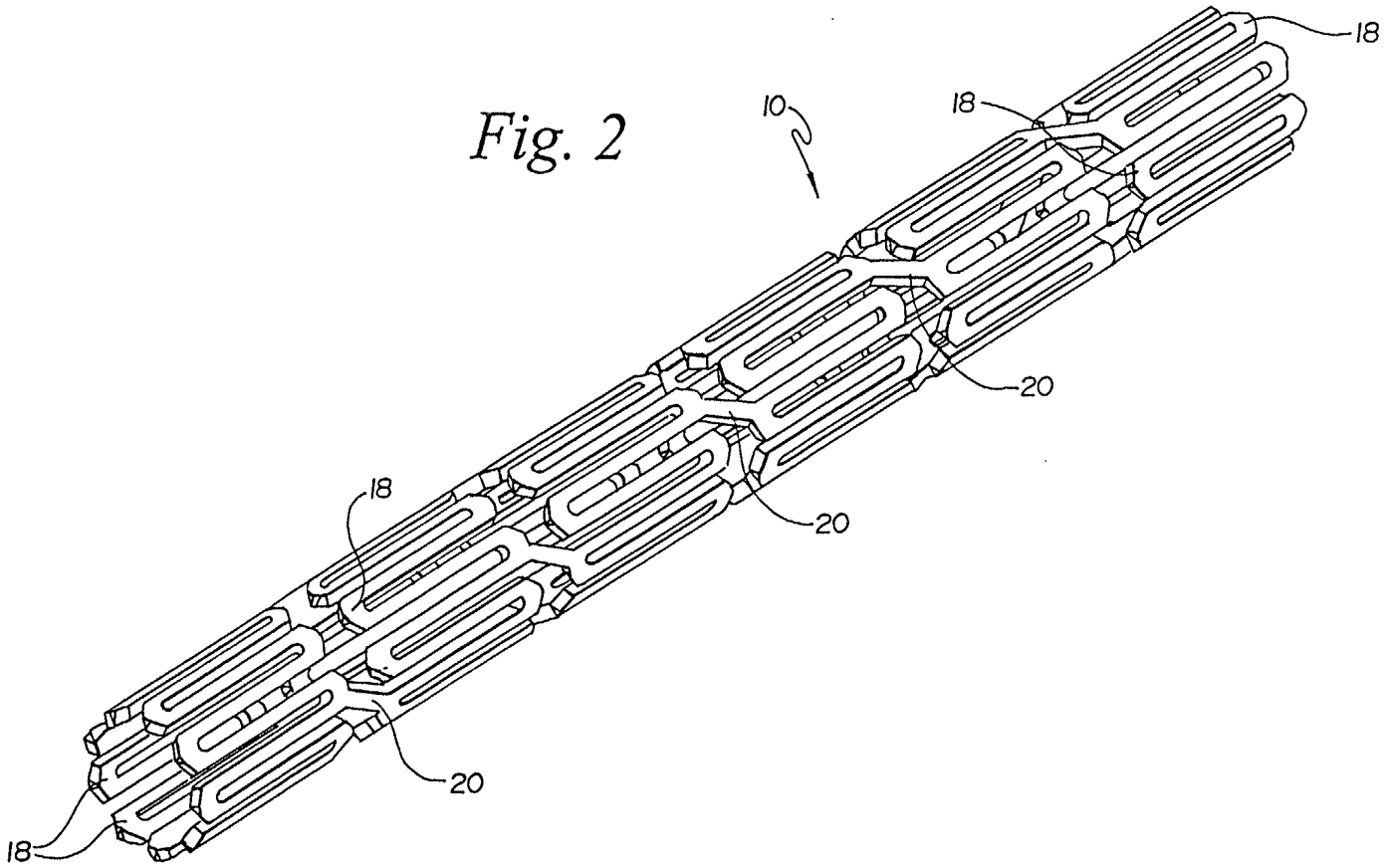
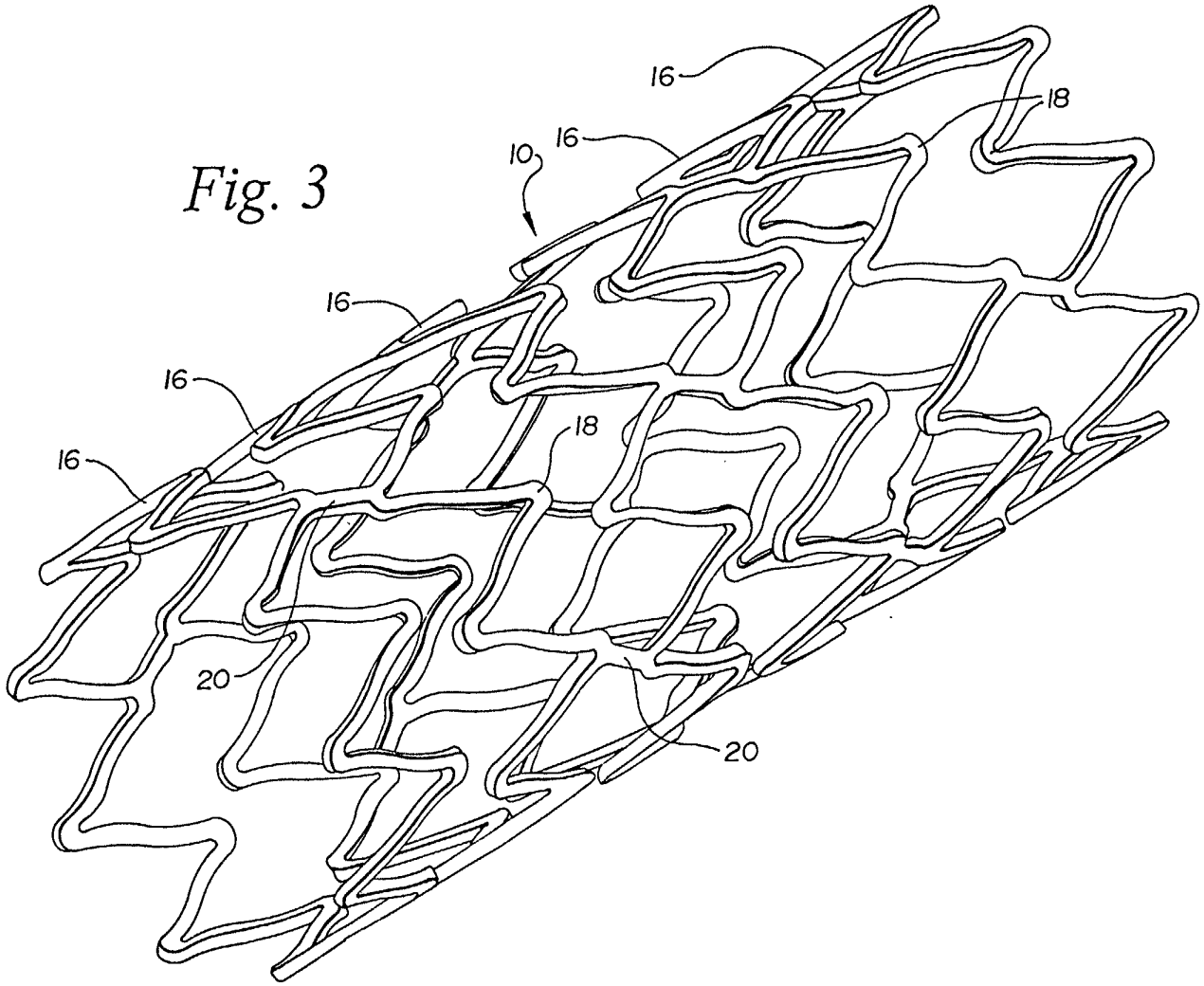


Fig. 3



UTILITY/DESIGN PATENT

Docket No. S63.2-5605

DECLARATION

As a below-named inventor, I(we) hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type:

- ☐ original
- ☐ design
- ☐ supplemental
- ☐ national stage of PCT
- ☐ divisional
- ☐ continuation
- ☒ continuation-in-part (CIP)

INVENTORSHIP DECLARATION

My residence, post office address, and citizenship are as stated below next to my name;

I verily believe I am the original, first and sole inventor *(if only one name is listed below)* or an original, first and joint inventor *(if plural names are listed below)* of the subject matter which is claimed and for which a patent is sought on the invention entitled:

IMPROVED ARTICULATABLE EXPANDABLE STENT

the specification of which

a) ☒ is being filed concurrently herewith

b) ☐ was filed on _____ and assigned Serial No. _____

c) ☐ was filed as PCT International Application No. _____ filed on _____ and amended under PCT Article 19 on _____.

ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations §1.56 including information occurring between the filing date of any prior application of which the present application is a continuation-in-part.

☐ In compliance with this duty there is attached an information disclosure statement. 37 CFR 1.97.

PRIORITY CLAIM

I hereby claim foreign priority benefits under Title 35, United States Code, §119, of any foreign application(s) for patent or inventor's certificate or of any PCT international applications(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application for patent or inventor's certificate or any PCT international applications(s) designating at least one country other than the United States of America filed by me having the same subject matter having a filing date before that of the application on which priority is claimed.

a) ☒ no such applications have been filed.
b) ☐ such applications have been filed as follows:

COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 37 USC 119
			☐YES NO☐
			☐YES NO☐
			☐YES NO☐
			☐YES NO☐

CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATIONS(S) UNDER 35 U.S.C. §120

I hereby claim the benefit under Title 35, United States Code, §120 of any United States applications(s) or PCT international applications(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior applications(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56 which occurred between the filing date of the prior applications(s) and the national or PCT international filing date of this application.

a) ☐ no such applications have been filed.
b) ☒ such applications have been filed as follows.

U.S. APPLICATIONS	
SERIAL NUMBER	U.S. FILING DATE
1.08/396,569	March 1, 1995
2.	
PCT APPLICATIONS DESIGNATING THE U.S.	
PCT APPLICATION NO.	PCT FILING DATE
3.	

I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Telephone calls and correspondence should be directed to: **Oliver F. Arrett,** VIDAS, ARRETT & STEINKRAUS, P.A., Suite 1540, 920 Second Avenue South, Minneapolis, MN 55402-4014, Telephone: (612) 339-8801, Facsimile (612) 349-6858.

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Inventor's signature: Brian J. Brown

Date: 8-2-95

Citizenship: United States of America

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Residence:
(If different than above)

Second Inventor

Full name: Michael L. Davis

Inventor's signature: Michael L. Davis

Date: 8-2-95

Citizenship: United States of America

Post office Address: 22020 Stratford Place
Shorewood, Minnesota 55331

Residence:
(If different than above)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s):	Brian J. Brown et al.
Title:	IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT
Filed:	☒ concurrently herewith
	☐ on _____ and assigned Serial No. _____

Box Patent Application
Commissioner for Patents
Washington, D.C. 20231

Docket No.: S63.2-9216

CORRESPONDENCE ADDRESS OF LAW FIRM

Vidas, Arrett & Steinkraus P.A. would like to make the following correspondence address of record. Please send all correspondence for this application to the address as follows:

CUSTOMER NUMBER 490
whose present address is
Vidas, Arrett & Steinkraus P.A.
Suite 2000
6109 Blue Circle Drive
Minnetonka, MN 55343-9131

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

By: _____
Jonathan Grad
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